

**DRAFT April 16 2009**

**Remarks of Rep. Henry A. Waxman**  
**Chairman, Committee on Energy and Commerce**  
**United States House of Representatives**  
**Before The Food and Drug Law Institute**  
**April 22, 2009**

I want to express my thanks to the Food and Drug Law Institute for inviting me to speak with you today.

You are a non-profit organization – perfectly in sync with today’s economy.

This is a particularly opportune time to be holding your meeting.

That’s because we are celebrating the 25<sup>th</sup> anniversary of the passage and enactment of the Drug Price Competition and Patent Term Restoration Act, also known as the Waxman-Hatch Act. I am very proud of this legislation and the role it has played in bringing affordable drugs to Americans. And indeed, to patients around the world. I am particularly proud of the careful balance in Waxman-Hatch between ensuring access to safe and affordable drugs and providing adequate incentives for innovation. The 25-year history of Waxman-Hatch proves that the balance we struck was sound: generic competition has lowered drug prices without harming innovation.

And I am delighted that Orrin Hatch, who helped strike that balance, will also be here to address this conference.

Generic drugs play a critical role in promoting global public health. Where they are available, they promote competition—which in turn lowers drug prices. Lowering drug prices reduces our overall health care bill. More importantly though, lower drug prices mean access for many patients who might not otherwise be able to afford their medications. Today in the U.S., a

remarkable 67 percent of prescriptions are filled with generic medicines – saving consumers and the federal and state governments tens of billions of dollars annually.

Competition also fosters innovation by forcing companies to bring new products to market to replace revenues from older products. And that means more lives saved when improved medications are introduced in the market.

During these difficult economic times, people are searching for ways to reduce health care costs—without compromising quality of care. Generic drugs are one important answer.

So we need to make sure that policies are in place around the world that foster widespread access to generic drugs.

We also need to make sure that generic competition is brought to bear on all types of drugs.

### **Generic Biologics**

Unfortunately, for one of the most important and fastest growing types of drugs, there currently is no competition—I'm referring of course to biologics.

Biologics are one of the fastest growing and most expensive categories of drugs, frequently costing tens of thousands—even hundreds of thousands—of dollars per year. These drugs are often life-saving.

When we were drafting the original Waxman-Hatch Act 25 years ago, biologics were essentially non-existent. So they were not explicitly covered under the law. The result is that FDA is now left without a clear pathway for approving low-cost competing versions of these drugs, even after patents have expired.

Indeed, patents on many biopharmaceuticals have already expired and many billions worth of these drugs will come off patent over the coming years. But there will be no generic

competition. And employers, insurers, and the federal government will continue to pay the staggering monopoly prices we have today. Some would say that FDA already has sufficient authority under the Public Health Service Act to create an administrative pathway for approving abbreviated applications for biologics. But I believe that a legislative pathway is preferable-- because it offers the opportunity to provide incentives for innovation and a mechanism for early resolution of patent disputes.

That's why I have introduced a bipartisan bill -- "The Promoting Innovation and Access to Life-Saving Medicines Act" -- to end permanent monopolies for biotech drugs while maintaining adequate incentives for innovation. A workable scientific, regulatory and legal pathway for biogeneric and biosimilar pharmaceuticals will ensure more affordable medications for everyone. And I believe it will spur true innovation in the biotech market.

I am confident that this is the year we will finally see this legislation enacted.

We now have a President who is committed to ensuring that every American has quality, affordable health care and coverage. A President who understands we cannot achieve that commitment without rationalizing our health care system and securing more competition within the pharmaceutical marketplace. A President who in his campaign and his platform embraced the need for a workable pathway for biogenerics.

The Energy and Commerce Committee, which I am privileged to chair, has broad jurisdiction over health legislation. Seeing a biologics pathway enacted is one of my highest priorities for this year.

Over the past couple of years, we have made remarkable progress toward the goal of creating such a pathway. We've come much farther towards the enactment of that pathway much faster than I had originally expected.

At least part of the reason for this tremendous progress is the desperation patients and payers feel about the skyrocketing cost of biotech drugs. At a hearing I held two years ago, representatives

from the state of Illinois and from the California state retirement fund made clear that their situation was urgent. They testified that if the cost of biologics continued to rise at current rates, they would very soon have only two choices: To transfer a substantial part of the cost to plan participants, effectively making these drugs unaffordable. Or to stop paying for them altogether. Neither choice is acceptable.

Other payers and consumers agree that the cost of biologics is unsustainable. Within a few months of the first introduction of the bill in 2006, an impressive and effective coalition of businesses, consumer and patient groups, and purchasers had come together to push for the rapid passage of a generic biologics pathway.

We've learned a great deal since we started this debate. We've heard from the FDA that the science exists now for the Agency to begin reviewing and approving at least some biosimilars today. We've heard that the FDA wants the flexibility and authority to use its best scientific expertise to determine approvals.

We've also heard from those who don't want to see generic competition in the biopharmaceutical arena. A lot of what we've heard is reminiscent of what was said twenty five years ago when we were working on Waxman-Hatch. That generic drugs would not be as safe and effective as brand name drugs. That allowing generic competition would harm innovation. Those assertions have been proven wrong time and again.

We need a workable approval process that gets these affordable life-saving medicines to patients in need sooner rather than later.

One of the most contentious issues is the term of exclusivity awarded to brand name companies. The debate about the appropriate number of years has already been distorted by drastically inflated numbers based on assertions not grounded in hard data. I have repeatedly asked for data showing exactly how many years of exclusivity are necessary. The number of years the industry says it needs has morphed over the couple of years we've been debating this bill.

It began with an assertion that the correct number is 10 years because that's what the EU gives. More recently, the biotech industry has become attached to the figure of 14 years. Essentially, the biotech industry wants Congress to *triple* the exclusivity we provided to traditional drugs. A changing series of arguments has been advanced to justify this extraordinary request.

In assessing those arguments, I begin with a basic premise: the balance we struck in Waxman-Hatch has worked well for 25 years. It has given us access to affordable drugs and it has not damaged innovation. Pharmaceutical R&D expenditures have not just been maintained, but have steadily risen throughout those 25 years.

Given that premise, I need some hard evidence that there is something fundamentally different about the biotech drug marketplace. A difference that justifies tripling the period of exclusivity that has been proven adequate for traditional drugs.

I have not seen that evidence.

The most recent argument advanced for 14 years is that it is needed to recoup the costs of developing a new biotech drug. The biotech industry is distributing a paper arguing that the average term a biologic takes to "break even" is around 14 years. And that 14 years is therefore the number of years of non-patent exclusivity they need to sustain innovation.

Frankly, I'm dubious about the numbers in the industry's paper. There are strong arguments from the other side of the debate that many of the assumptions in that paper were flawed. If you start with more plausible assumptions you get a much lower break-even point—somewhere around seven years.

Even more relevant to my concerns, what the paper makes clear is that there is *no difference* in the so-called break-even period between biotech drugs and traditional drugs. The break-even point was calculated by the authors of the paper using the costs and risks of bringing a biologic to market. But according to the same authors, the costs of bringing a biologic to market are *the same* as those of bringing a traditional drug to market, and the risks of failure are actually lower.

In short, the authors cannot point to any significant differences between traditional drugs and biologics in when they will reach the break even point. So, the paper does not give us any reason why we should give biologics 3 times the exclusivity that has been proven adequate for traditional drugs.

So the break-even point is *not* the answer to the question of how much more *non-patent* exclusivity period biotech drugs need over traditional drugs.

The “break even” point may instead be the answer, if calculated with appropriate assumptions, to the question of how much monopoly protection *from any source* the drug industry needs to encourage innovation. But remember— in our system, *patents* are supposed to provide the monopoly protection necessary to encourage innovation. The whole point of patent term *extensions*—remember Title II of Waxman-Hatch?—was to ensure that patents on drugs and biologics run long enough after approval to provide adequate incentives for innovation.

So the break-even argument really boils down to something else. The biotech industry is really arguing that they need non-patent exclusivity because patent protection doesn’t work for them.

And, indeed, the biotech industry has sometimes argued – though conspicuously not in the patent reform debate -- that the patents on biotech drugs are so narrow that they will not cover biosimilars with slightly different chemical structures. I have repeatedly asked for evidence, like supporting caselaw, that this assertion is true. But I have received nothing to back it up. Certainly, the most well-reported case – Amgen’s successful defense of its EPO [ee’poe] patents -- supports the opposite view. Amgen’s patents on EPO [ee’ poe] are apparently so strong the courts have decided that they protect EPO from competition for something like 25 years from the date EPO was first approved. This is not exactly a compelling argument that biotech patents are too weak to protect against biosimilars.

In sum, we have yet to see any persuasive evidence that the Waxman-Hatch balance that has been so successful for traditional drugs will not also work for biologics.

As we go through the process of crafting a consensus bill, I am determined to prevent inflated numbers from artificially increasing the final number of years we grant in exclusivity.

If the Congress ignores the lessons we learned about balance in Waxman-Hatch and passes a bill that puts too much weight on one side of the scale – the side of giving huge profits to the drug industry-- we will lose a huge opportunity and damage the affordability and access to these drugs well into the future.

I can not support such a bill. Because, as I said at the outset, there is reason to believe that FDA can create an abbreviated pathway for biologics without new legislation. Using this bill to enshrine in law unprecedented and excessive monopoly periods would therefore be a windfall benefit for the pharmaceutical industry-- and worse than nothing for consumers and payers.

Rather than enact a bill that defeats its central purpose—to make biotech drugs affordable--I will encourage FDA to develop a pathway using its existing authority. But that course is not ideal. I remain hopeful that we can achieve the same strong balance between fostering innovation and making affordable medicines available to consumers that we did in Waxman-Hatch.

### **Food Safety**

I want to turn briefly to discuss food safety issues.

Americans do not need another deadly outbreak to understand that our food safety system is in desperate straits. But we got one earlier this month – with pistachios.

The current state of our food safety system is dangerous not just for the American public, but also for the food industry itself.

We must act now to address this problem. Over the next few months, the Energy and Commerce Committee will move a strong food safety bill.

Chairman Emeritus Dingell, Chairman Pallone, and Chairman Stupak have provided us with an ideal starting point in their FDA Globalization Act of 2009. I commend them for their work on this bill. Using this bill as a foundation, we will seek assistance from President Obama's FDA to implement some common-sense food safety measures that are long overdue.

The Dingell bill addresses all of the product classes regulated by FDA—foods, drugs, medical devices, and cosmetics. It is a strong bill that makes a critical contribution toward addressing the host of pressing problems confronting FDA. As many of you know, however, the Committee has made the strategic decision to move forward with the just the food safety provisions at this time. FDA's food program is desperately in need of a revamping—we cannot wait to fix it. But we will return to looking at all of the other sections of the Dingell bill as soon as we address food safety.

My goal is to see that the House produces as strong a food safety bill as possible.

Mr. Dingell and Rep. Rosa DeLauro have both already started us down a path toward that goal by introducing their very strong pieces of legislation. Although we are using the Dingell bill as a foundation, we will draw from the good work Ms. DeLauro has done in her bill as we look at this issue.

As we move forward, we will also draw upon the work our Subcommittee on Oversight and Investigations. The Subcommittee's hearing examining the recent salmonella outbreak caused by the Peanut Corporation of America provided a powerful glimpse into just how extensive the problems plaguing our food safety system truly are.

It is clear that we need to give FDA some basic authorities that will enable it to do its job. As the O&I hearing illustrated, FDA does not have the authority to routinely access records

documenting the steps that manufacturers take to assure safety. FDA also lacks modern and flexible enforcement tools, like administrative civil monetary penalties. FDA's penalty structure is antiquated and wholly inadequate. The most that the owners of PCA could have been charged with under the Food, Drug, and Cosmetic Act is a misdemeanor. FDA's statute is literally from another century. Other agencies have modern enforcement tools and we must ensure that FDA gets them too.

The hallmark of the food safety bill must be a shared responsibility for food safety oversight between FDA and industry. I have been concerned about proposals that seem to over-rely on inspections by FDA as the cure for our ailing food safety system. With well over 300,000 registered food facilities around the world, it is abundantly clear that we simply cannot expect FDA to inspect our way out of this problem. FDA alone cannot bear the responsibility for ensuring food safety when companies here choose to purchase cheaper ingredients from less regulated foreign countries.

Effective solutions will include a combination of increased resources and enhanced authorities for FDA. But it will also include a strong focus on industry's responsibility for overseeing the safety of their own products—and accountability when they fail.

Preventing problems from ever occurring in the first place is critical. That is first and foremost a responsibility of industry—they are the ones producing the food and familiar with their own processes.

To be sure, FDA also plays a role in prevention—there must be an effective audit system in place, and FDA must have strong enforcement tools at its disposal for failures.

Food producers must be required by law to put strong preventive control plans in place under which they monitor and protect against contamination. FDA must also have the ability to set certain minimum requirements for those plans for specific food types when FDA thinks that is necessary. I was heartened to hear that GMA has now decided to support that specific grant of authority to FDA.

Let me say a few words about the notion of a so-called “single food agency.” A lot of good points have been made about the need to improve our fragmented system and ensure that food safety is given appropriate attention by our regulatory agencies.

But reorganizing large federal bureaucracies takes a great deal of time — and this is time we do not have when it comes to food safety. We must act now. We have to concentrate the additional resources we can get at this point on the job at hand. Our first goal should be to address the problems that plague this program where it currently sits. After we finish that job, we can consider whether a reorganization is necessary, and, if so, how to go about it.

We have a challenging job ahead of us, but we also have many reasons to be optimistic. In his budget, President Obama called for over \$1 billion for FDA’s efforts to increase and improve inspections, domestic surveillance, laboratory capacity, and domestic response to prevent and control food borne illness.

This food safety crisis calls for strong leadership at the agency. So I was encouraged that President Obama nominated Margaret Hamburg to head the FDA, with Dr. Josh Sharfstein as her deputy. Dr. Hamburg is an excellent appointee, and I look forward to working with her and with Dr. Sharfstein.

### **Full Committee Priorities**

Before I conclude, I want to speak very briefly about two of President Obama’s top priorities — and they are mine as well — because they will be central to the Energy and Commerce Committee’s work this year.

First, and directly related of course to what I have been discussing this morning, is health care reform.

There are many ways to go about health care reform, and there undoubtedly will be a spirited debate about the best approach. But what is clearly the best approach is a bill that we can pass and that secures the goal of universal coverage, sensible controls on cost, and assurance of quality care. My expectation is to complete committee consideration and have the bill ready for floor action before the August recess.

Second is global warming. We are at a critical time in history and have a tremendous opportunity to substantially reduce greenhouse gas emissions. Yesterday Energy Subcommittee Chairman Ed Markey and I released a discussion draft of new clean energy legislation that will create millions of clean energy jobs, put America on the path to energy independence, and cut global warming pollution. Our goal is to strengthen our economy by making America the world leader in clean energy and energy efficiency technologies. We have looked to science to guide us as we've developed this legislation. Our plan is to move the bill through committee to the House floor by the Memorial Day recess.

By electing Barack Obama President, the American people expressed a desire to have their faith in government restored. We face very difficult challenges, but we also have a great opportunity to make permanent structural changes that are worthy of the hopes the American people have placed in our government.

Some say we should put all other goals on hold to tackle the devastating problems we are facing with the economy. I view it completely differently. I believe that reforming our health care system and pursuing energy policy that charts a new course toward clean energy are integral to restoring our economy.

Thank you.